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Annette Roy, Regulatory and Technical Support 2022-07-14 Christine Laforge RT, Technical Representative

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# Product Name: MicrewTube™ Catalogue No.: T365-5\_S series This document replaces any previous version 1. Product Description:

5ml MicrewTube:Sterile, Threaded, conical bottom tube with assembled cap

- > Available colors:
  - Natural and Amber

# 2. Packaging:

Case:

2 packages of 100 units / 200 units per case

## 3. Product Specifications:

- Material:
  - Polypropylene tube
  - Polyethylene cap
- Certified RNase, DNase, Pyrogen and DNA Free
- ▶ Gamma radiation sterilized at a SAL of 10<sup>-3</sup>; specified dose between 6.5 kGy and 13.5 kGy
- Temperature range: -196°C to +121°C for the tube only

## -196°C to +100°C for the cap

- > Tube without cap is Autoclavable at 121°C, for up to 30 minutes
- Molded graduation markings incremented at every 0.5ml and up to 5ml
- > Etched surface on side of tube for sample identification
- Centrifuge resistant at up to 25 000g

# 4. Standards and Conformity:

- > ISO 2859-1:
- > FDA:
- CONEG / RoHS:
  - Plastics and colorants are in conformity with

Sampling and inspection procedures

Resin conforms to FDA 21 CFR 177.1520

CONEG / RoHS standards for heavy metals

- > REACH (SVHC):
- > LATEX:

- Plastic is in conformity to REACH standards Material is Latex Free
- BSE / TSE:Material is BSE / TSE Free



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## 5. Quality Assurance:

- Clear, no presence of contamination in plastic
- Visual attributes
- Closure verification

#### 6. Traceability:

**Lot No. Composition:** 8 to 9 digits

#### > The lot number can be found in one or all of these locations:

- 1. On exterior case label
- 2. On label inserted inside the master case
- 3. On the inner bag

#### 7. Storage Conditions:

- Store at room temperature in normal warehouse conditions
- > Avoid temperature variations and humidity
- Protect from any possible contamination
- Protect from any damage to the packaging

#### 8. Recommended Use:

- > Verify proper cap closure when using biohazard material and / or chemical reagents
- > Follow chemical resistance chart recommendations
- > For use in automated equipment, follow the equipment manufacturer's instructions
- > Should be used only in the gas phase of Liquid Nitrogen

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